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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/526,802      | 03/16/2000  | Jagdish Parasrampuria | 4600-0131.30        | 1577             |

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[REDACTED] EXAMINER

QAZI, SABIHA NAIM

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1616     | 19           |

DATE MAILED: 04/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                      |  |
|------------------------------|------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 09/526,802             | PARASRAMPURIA ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |  |
|                              | Sabiha Naim Qazi       | 1616                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 December 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 10 and 36-39 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 9 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

Acknowledgement is made of the response and request for reconsideration on 12/23/02. Amendments are entered. Claims 1-10 and 36-39 are pending. NO claim is allowed at this time. Instant invention is drawn to formulations and method of use of form I polymorph and form II polymorph of dehydroepiandrosterone (DHEA).

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. Since during interview on 8/22/02 all the aspects of patentability of the invention of being a polymorph was discussed in detail, Examiner is maintaining the rejection for the same reasons as set forth in our previous office action.

Claims 1-10 and new claims 36-39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Morales et al. (US 5,407,927) and Loria et al. (US 5,077,284) in combination of Chang et al. (DN 123:265915, HCAPLUS, abstract of J. Pharm. Sci. (1995), 84(10), 1169-79). These references teach formulations, methods and polymorphic forms of DHEA, which embraces Applicant's claimed invention. See the entire documents especially lines 37-62, col. 1; lines 4-10 and lines 59-66, col. 12 in US 5,077,284 and lines 59-68, col. 2; lines 25-58, col. 3 and table 2 in col. 7 in US 5,407,927. These references teach the formulation of DHEA for various methods of treatments.

Chang et al. teaches solid-state crystallization of DHEA and its polymorph (forms I-III). Furthermore, it discloses that form I is more stable than others. See

abstract in the article AQ in form 1449. Instant claims differ from the reference in claiming formulations and method of preparation of specific polymorphic form I of DHEA.

It would have been obvious to one skilled in the art at the time when instant invention was made, to be motivated to prepare additional beneficial preparations and formulations of DHEA by using any polymorphic form of this compound especially form I and would expect the same results because when the compositions of the compound would be prepared, it would be the same after dissolving in the solvent, no matter what polymorphic form exists in the solid state. Motivation is to prepare formulations, of DHEA form I polymorph because form I is taught to be more stable, for the treatment of systemic lupus erythematosus, to prevention or reduction of loss of bone density, and treatment of chronic fatigue syndrome or fibromyalgia. One would expect same properties with the polymorphic form I of DHEA formulation. Different polymorphic forms are not patentable over each other in absence of unexpected properties.

C13 NMR in claims for polymorphic form has been considered, but as was said earlier that prior art compound contains polymorph I therefore, in composition this will not patentability distinct.

It had been held that by changing the form, purity or other characteristics of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art.

*In re Cofer*, 53 CCPA (1966) 830, 835, 354 F2d 664, 668, 148 USPQ 268, 271.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Telephone Inquiry Contacts**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



SABIHA QAZI PH.D  
PRIMARY EXAMINER

April 2, 2003